# Test Plan and Executive Summary for

# IRGANOX 1035

# Thiodiethylene bis (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)

# CAS No. 41484-35-9


| | |
|---|---|
| Name of Sponsoring Organization: | Ciba Specialty Chemicals Corporation |
| HPV Registration Number: | |
| Technical Contact Persons: | Richard Balcomb and Shailaja Rao |
| Address: | 540 White Plains Road<br>Tarrytown, New York 10591 USA |
| Tel: | (914) 785-2000 |
| Fax: | (914) 785-4147 |
| DATE: | AUGUST 8, 2003 |


**RECEIVED**
**OPPT CBIC**

**2003 AUG 22 PM 1:52**

**SUMMARY TABLE**

| **CAS No. 41484-35-9** | | | |
|---|---|---|---|
| **PHYSICAL/CHEMICAL ELEMENTS** | **DATE** | **RESULTS** | **FULFILLS REQUIREMENT** |
| Melting Point | 2001 | 63.0 – 68.0 $^{o}$C | Yes |
| Boiling Point | 2003 | 664.94 $^{o}$C | Yes |
| Vapor Pressure | 2003 | 7.5 x $10^{-18}$ mm Hg | Yes |
| Partition Coefficient | 2003 | log Kow > 10.36 (estimated) | Yes |
| Water Solubility | 2003 | < 1 mg / liter (measured)<br>4.55 x $10^{-7}$ mg/ L (estimated) | Yes |
| **ENVIRONMENTAL FATE AND PATHWAYS ELEMENTS** | | | |
| Photodegradation | 2003 | For reaction with hydroxyl radical, predicted rate constant = 60.98 x$10^{-12}$ $cm^3$/molecule-sec. Predicted half-life = 2.103 h. | Yes |
| Stability in Water / Hydrolysis | 2003 | EPIWIN model could not evaluate this structure. Experimental determination is not practical due to low water solubility. | NA |
| Fugacity | 2003 | Predicted distribution using Level III fugacity model<br>Air 0.00046 %<br>Water 1.04 %<br>Soil 44.4 %<br>Sediment 54.6 % | Yes |
| Biodegradation | 1984 | Not biodegradable<br>10 mg/L: 7% in 28 days<br>20 mg/L: 2% in 28 days | Yes |
| **ECOTOXICITY ELEMENTS** | | | |
| Acute Toxicity to Fish | 1984 | Zebra Fish : $LC_{50}$ (96 h) > 57 mg/L | Yes |
| | | Rainbow Trout: $LC_{50}$ (96 h) > 61 mg/L | |
| Toxicity to Aquatic Plants | 1993 | $EC_{50}$ (0-72 h) > 41 mg/L | Yes |
| Acute Toxicity to Aquatic Invertebrates | 1984 | i) $EC_{50}$ (24 h) > 4.4 mg/L | Yes |
| | 2002 | ii) $EC_{50}$ (24 h) > 100 mg/L | |

SUMMARY TABLE (CONTINUED)

| **CAS No. 41484-35-9** | | | |
|---|---|---|---|
| **HEALTH ELEMENTS** | **DATE** | **RESULTS** | **FULFILLS REQUIREMENT** |
| **Acute Toxicity** | 1982 | Rat: $LD_{50}$ (Oral) > 5,000 mg/kg | Yes |
| | 1975 | Rabbit: $LD_{50}$ (Dermal) > 3,000 mg/kg | |
| | 1975 | Rat: $LD_{50}$ (Inhalation) > 6,300 mg/ $m^3$ | |
| **Genetic Toxicity** | | | |
| In Vitro (Ames) | 1984 | Ames Test - Salmonella typhimurium: No increase in mutations with or without metabolic activation (at doses of 20, 80, 320, 1280 and 5120 ì g/ 0.1 ml) | Yes |
| In Vivo (Nucleus Anomaly Test) | 1984 | No Nucleus anomalies found in Chinese hamster bone marrow cells following oral doses of 875, 1750 and 3500 mg/kg | Yes |
| | | | |
| **Repeated Dose Toxicity** *Subchronic Toxicity* | | | |
| i) 90-Day oral toxicity study in rats | 1983 | NOEL = 60 ppm | Yes |
| ii) 90-Day oral toxicity study in rats | 1973 | NOEL < 10000 ppm | |
| iii) 90-Day oral toxicity study in beagle dogs | 1973 | NOEL = 2000 ppm | |
| | | | |
| **Reproductive Toxicity** | | No significant effects on reproductive organs in available subchronic tests with rats, mice and dogs. | Requirement will be met based on results of subchronic studies and the proposed developmental study. |
| **Developmental Toxicity** | | Not Available | Testing Proposed |